Sofia® Analyzer and RSV FIA

QUICK REFERENCE INSTRUCTIONS

For use with the Sofia Analyzer only.

Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

IMPORTANT! Read instructions carefully before beginning. The test procedure below is unique to the Sofia RSV FIA and may differ from other Sofia FIA procedures.

Test Procedure

NOTE: *The procedures for testing swab specimens versus aspirate/wash or specimens in viral transport media are different. Read carefully.*

All specimens must be at room temperature before testing.

Expiration date: Check expiration date on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Nasopharyngeal Swab Test Procedure

1

Verify that the Sofia Analyzer is set to the desired Analyzer Mode: **Walk Away** or **Read Now.** See the "Using the Sofia Analyzer" section for more information.

2

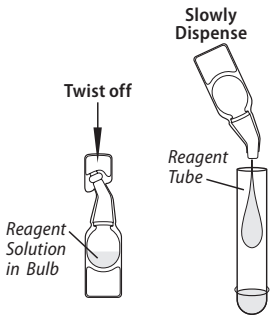
Prepare Reagent:

a) Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.

b) Twist off the tab.

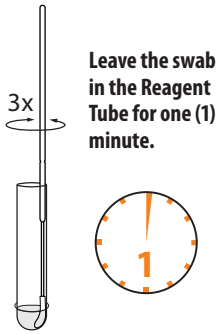
c) Slowly dispense all of the Reagent Solution into the Reagent Tube.

d) Gently swirl the Reagent Tube to dissolve its contents.



3

Place the patient swab sample into the Reagent Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Reagent Tube.



4

Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.

5

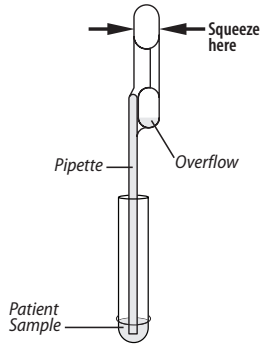
Fill the provided **small, clear** fixed volume pipette with patient sample from the Reagent Tube.

To fill the fixed volume pipette with the patient sample:

a) FIRMLY squeeze the top bulb.

b) Still squeezing, place the pipette tip into the patient sample.

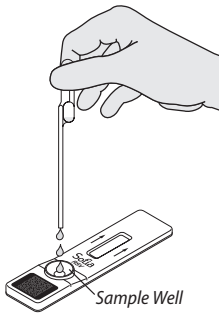
c) With the pipette tip still in the sample, release pressure on bulb to fill the pipette.



6

Firmly squeeze the top bulb to empty the contents of the **small, clear** fixed volume pipette into the Cassette sample well. Extra liquid in the overflow bulb is OK.

NOTE: The fixed volume pipette is designed to collect and dispense the correct amount of patient sample. Discard the pipette in your biohazard waste.



7

Proceed to the next section, "Using the Sofia Analyzer," to complete the test.

Nasopharyngeal Aspirate / Wash or Specimens in Viral Transport Media Test Procedure

1

Verify that the Sofia Analyzer is set to the desired Analyzer Mode: **Walk Away** or **Read Now.** See the "Using the Sofia Analyzer" section for more information.

2

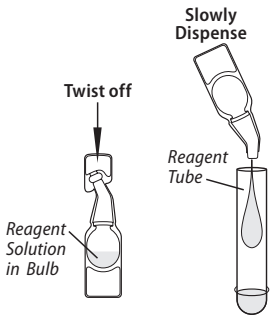
Prepare Reagent:

a) Flick or shake the Reagent Solution vial down so that all fluid is in the bulb.

b) Twist off the tab.

c) Slowly dispense all of the Reagent Solution into the Reagent Tube.

d) Gently swirl the Reagent Tube to dissolve its contents.



3

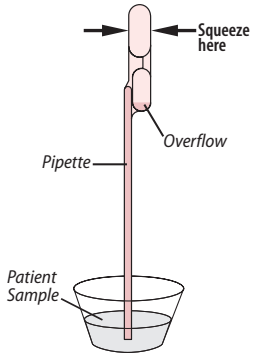
Fill the provided **large, pink** fixed volume pipette with patient sample from the collection cup.

To fill the fixed volume pipette with the patient sample:

a) FIRMLY squeeze the top bulb.

b) Still squeezing, place the pipette tip into the patient sample.

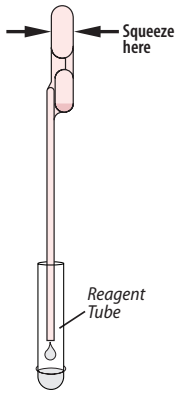
c) With the pipette tip still in the patient sample, release pressure on bulb to fill the pipette.



4

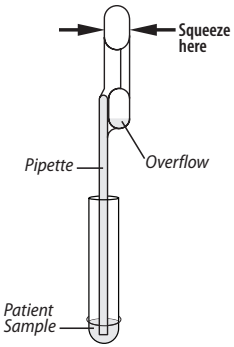
Firmly squeeze the top bulb to empty the contents of the **large, pink** fixed volume pipette into the Reagent Tube. Extra liquid in the overflow bulb is OK.

NOTE: The fixed volume pipette is designed to collect and dispense the correct amount of patient sample. Discard the pipette in your biohazard waste.



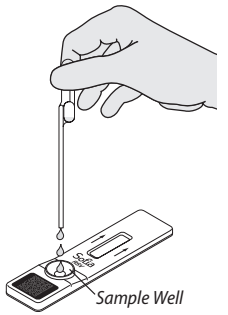
5

Fill the provided **small, clear** fixed volume pipette with patient sample from the Reagent Tube.



6

Firmly squeeze the top bulb to empty the contents of the **small, clear** fixed volume pipette into the Cassette sample well. Extra liquid in the overflow bulb is OK. Discard the pipette in your biohazard waste.



7

Proceed to the next section, "Using the Sofia Analyzer," to complete the test.

Using the Sofia Analyzer

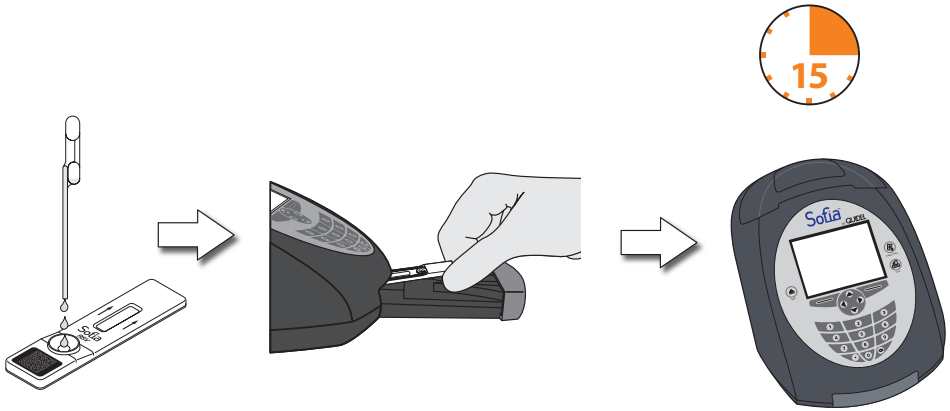
WALK AWAY/READ NOW MODES

Refer to the Sofia Analyzer User Manual for operating instructions.

The Analyzer may be set to two different modes (Walk Away and Read Now). The procedures for each mode are described below.

WALK AWAY MODE

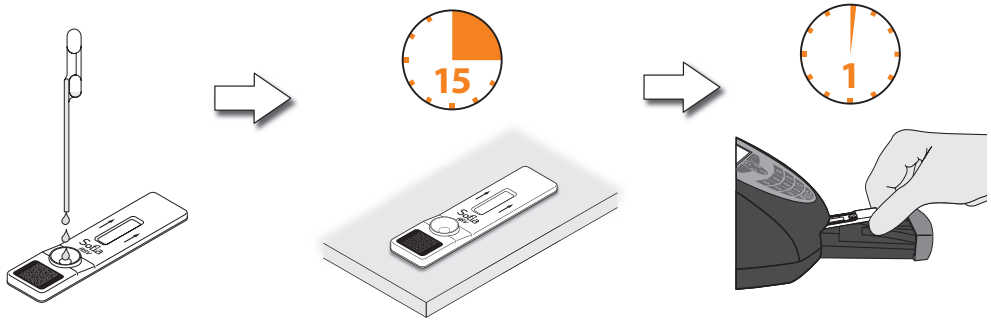
In Walk Away Mode, the user **immediately** inserts the Cassette into the Analyzer. The user then returns after fifteen (15) minutes to get the test result. In this mode, the Analyzer will automatically time the test development before scanning and displaying the test result.



READ NOW MODE

Allow the test to develop for the FULL fifteen (15) minutes BEFORE placing it into the Analyzer.

The user must first place the Cassette onto the counter or bench top for fifteen (15) minutes (outside of the Analyzer) and manually time this development step. Less than fifteen (15) minutes may result in false negative results. Then, the user inserts the Cassette into the Analyzer. In Read Now Mode, the Analyzer will scan and display the test result within one (1) minute. **Note:** Results will remain stable for an additional fifteen (15) minutes after the recommended development time of fifteen (15) minutes.

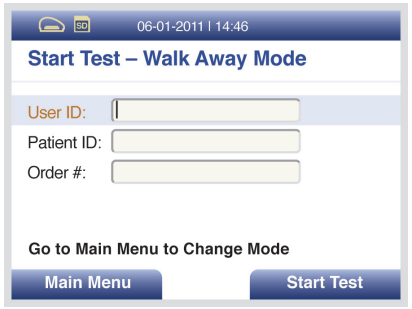


Using the Sofia Analyzer *(Cont.)*

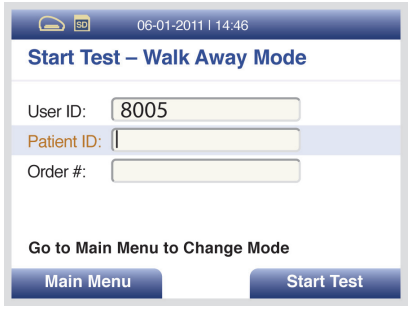
RUN TEST

1. Input the User ID using the handheld barcode scanner or manually enter the data using the key pad.

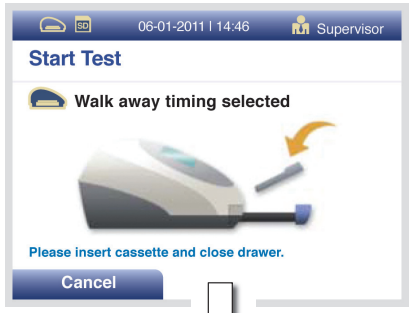
NOTE: *If you mistakenly scan the wrong barcode, use the Arrow Keys on the Sofia Analyzer to re-highlight the field and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode..*



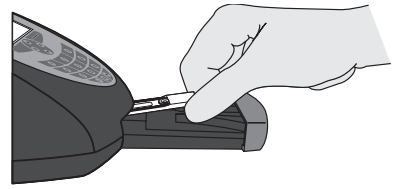
2. Input the Patient ID or Order # using the handheld barcode scanner or manually enter the data using the key pad.



3. Press Start Test and the Analyzer drawer will automatically open.



4. Verify that the correct mode, Walk Away or Read Now, has been selected. Insert the Cassette into the drawer. Then gently close the drawer.



5. The Analyzer will start automatically and display the progress. In Walk Away Mode, the test results will be displayed on the screen in approximately fifteen (15) minutes. In Read Now Mode, the test results will be displayed on the screen within one (1) minute. See Interpretation of Results section.

Interpretation of Results

When the test is complete, the results will be displayed on the Analyzer screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

Results: The Analyzer screen will display results for the procedural control being "valid or invalid." If the control is "invalid," retest with a new patient sample and new Test Cassette.

Reader Display	Interpretation
RSV: Positive	Positive Test for RSV (RSV antigen present)
RSV: Negative	Negative Test for RSV (no antigen detected)
RSV: Invalid Procedural Control: Invalid	Result Invalid

External Quality Control *(External Positive and Negative swabs are supplied in the kit)*

1. From the main menu, select Run QC.

2. Following the prompt on the screen, scan the QC Card (located on the kit box).

3. The Analyzer will prompt the user to select the desired mode (Walk Away or Read Now) and then to run the External Control Swabs.

4. Follow the Swab Test procedure of this Quick Reference Instructions to test each control swab, first the Positive swab followed by the Negative swab.

5. After both the Positive and Negative swabs have been run, the results will be displayed as "Passed" or "Failed."

INTENDED USE

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay.

Reference the Package Insert for *Warnings and Precautions, Specimen Collection and Handling,* and *Quality Control.*

ASSISTANCE

If the Sofia Analyzer or assay do not perform as expected, contact Quidel Technical Support (800) 874-1517 (in the U.S.), (858) 552-1100 (outside the U.S.), technicalsupport@quidel.com, or your local distributor.

Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert

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